ATTACHMENT 10

From: **Stan Hamilton** manager@rebotix-panama.com
Subject: Re: Intuitive Surgical da Vinci Endoscopic Instruments
Date: June 7, 2018 at 9:51 AM
To: Glenn Papit pipiczinc@gmail.com, Bob Overmars bob@bpimedical.com
Cc: chris.gibby@yahoo.com

Hi Bob,
Believe me, I feel and understand your frustration with this. The problem is that the reason they are asking for some sort of FDA approval is because that is the lie that they are being told by the intuitive rep, and if we allow them to set rules for the gamethat we can't possibly follow, then they win. I have seen an awful lot of 510k's and I have never seen one for a service process for a multi-use device, and sure someone at the FDA will go along with it and tell you the most conservative thing with the ideathat you could possibly resell the units, but that isn't reality. They will never give you anything beyond what you got in that email, which is a request to follow their process for marketing product.
I think the best approach is to get hospital admin to realize they are being duped - by explaining the reality of the situation - but that means getting past this dismissal being encouraged by intuitive. In my opinion, one way to do that is to make them realizethey are throwing away a LOT of patient and Hospital dollars and being financially and socially irresponsible if they don't properly consider this. In our experience, the more chance we have to get in front of them and really explain the truth of the situation,the more momentum swings to our side.
This is the best answer I can give you for your number 2 issue below, along with an offer to support any opportunity to break through the misinformation with key decision-makers, and I think it is important to have people involved that understand why throwingthis money away is not a good idea, which is not always the clinical people.

On the brochures, we have artwork done for this which can be customized by a resource in Florida, we just need to understand what points you would like to have highlighted there and agree on how we can communicate them, then we can get you artwork to print up what you need. I think Glenn/Chris can help with this, by getting you a current example and then I would be happy to help with the modifications you want made.

Thanks for your inputs, we truly appreciate your efforts and contributions to try and break this through.
Stan

From: Bob Overmars
Sent: Thursday, June 7, 10:45 AM
Subject: Re: Intuitive Surgical da Vinci Endoscopic Instruments
To: Glenn Papit, Stan Hamilton
Cc: chris.gibby@yahoo.com

Exhibit
DX 258

Guys,

Unfortunately none of this helps us make a sale….

The reps are going to need a “tool” to gain any sales traction on this.
Intuitive reps penetrated from the top down to insure they go back to intuitive after the counter runs out. Moreover, they’ve been doing this for years and years. The customer

counter runs out. Moreover, they've been doing this for years and years. The customer is convinced what Intuitive tells them is the gospel.

We need some rep tools, for example:
1. We need a handout/brochure that explains our position to overcome the objections the customer has after the Intuitive reps used their tool bag to lock us out.

2. Something / Anything from the FDA that eludes to the repair company not requiring 510K. Of course, it's straight forward to us as common knowledge you don't need a 501K to repair a multi use sterilizable instrument owned by the hospital. That generic statement is Not working with the customers.
They want something specific that says Intuitive, Endowrists, etc.

I may have mentioned this already, but I contacted University of Iowa hospitals and clinics who formed a Da Vinci XI Implementation Project (they also had an Intuitive rep or their team) and it was engrained in the whole team they had to send to Intuitive whenthe counter ran out.

In my 26 or so years of experience, we either jump in head first or walk away. I never make any money dipping one toe in the water and testing. Additionally, this always comes to head sooner or later. We start picking up a few from our relationship customers… The OEM reps starts to notice his commissions on that account are going down, he digs in, finds out we're now doing the repairs and he goes straight to the OR and his Dr. Relationships telling them we're using hammers and screwdrivers in the back yard garage.

All my local customers laugh them off and just tell my rep about it. The OEM reps who get to loud, I call them and invite them to our facility to educate them on the products thei selling. 50/50 take me up on my offer and we develop a relationship and theother half shut up and go away.

This will happen with Intuitive and more likely the rep will call his boss and it will eventually go back to the FDA. Dr. Rabang was real clear to me when he told me any repair company would be required to have a 510K. Even though we all know that doesn't apply. I even asked him under what authority would he have to require a 510K and he thought I was getting confrontational and didn't answer. So, I backed off.

Do you guys have a suggestion for any tools to overcome the customers objection(s)?

Kindest regards,
Bob Overmars
President - CEO

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On Jun 6, 2018, at 4:29 PM, Glenn Papit <pipiczinc@gmail.com> wrote:

Afternoon again my friend !

I've attached Stan's reply and spoke with him on the phone. He strongly suggests that you have no further need to engage the FDA with questions, as they have already demonstrated that they do not understand your intention to simply conduct a repair for a given hospital then return that repair to that same hospital. This is a common hospital repair process without sterilization or transfer of ownership. When asked the FDA will, in all likelihood, always provide the most conservative, controlling response. In thiscase no input is needed from them. Undoubtedly Intuitive will present the customer with a cornucopia of misconceptions which may include supposed FDA requirements. But in the end we're just doing a repair.

The decision is certainly yours as to the approach that BPI takes and I respect how you chose to proceed. Let me know what you wish to do next and how I can support.
Thanks very much Bob.

Glenn Papit
President
103 Shell Fall Drive
Apollo Beach, FL 33572
407-810-4176
pipiczinc@gmail.com
Pipicz Inc.

---------- Forwarded message ----------
From: **Stan Hamilton** <manager@rebotix-panama.com>
Date: Wed, Jun 6, 2018 at 6:50 PM
Subject: Re: Intuitive Surgical da Vinci Endoscopic Instruments
To: "chris.gibby@yahoo.com" <chris.gibby@yahoo.com>, Glenn Papit <pipiczinc@gmail.com>

Hi Glenn,
There is no need to respond to Dr. Rabang. Here we are revisiting the path that Rebotix went down in some agonizing detail over 2 years ago.
The key point here is that the FDA does not regulate the service of instruments owned by the hospital, so all of these answers (and references to regulations) that FDA is is providing apply only to a situation where Rebotix chose to place repaired product onthe market again (change of ownership). We do NOT do this, and we have no intention to do this. Dr. Rabang has no way to respond regarding the appropriateness of the repair, and he cannot answer this question for the hospital.
There is simply no reason to bring the FDA into a hospital service situation, where what we are doing does not alter the specification any differently than dozens of other service

processes that have been at work for years. Almost any service process altersthe original manufacturer's "specifications", because the labeling usually specifically says that the equipment should not be serviced by anyone but themselves.
In our case, we do not do any sterilization, all of that processing is done as normal by the hospital, and we do not alter the instrument specifications in any substantive way. The manufacturer can try to make a point to the hospital that the instrument isnot good to use beyond 10 uses, which of course they must do otherwise they make their robbery obvious, but we have proof to show different and at the end of the day it is the hospital's call to decide what is appropriate, not FDA.

Kind Regards
Stan
From: Glenn Papit <pipiczinc@gmail.com>
Sent: Wednesday, June 6, 2018 3:40:42 PM
To: Stan Hamilton; Chris.gibby@yahoo.com

Subject: Fwd: Intuitive Surgical da Vinci Endoscopic Instruments

Well Stan, here is where you get to shine ! Can you formulate an answer for Bob to reply to Cal Rabang (FDA) please. This seems to be very deep baloney but we need to answer to move forward. Really appreciate your help; please SHINE !

Glenn Papit
President
103 Shell Fall Drive
Apollo Beach, FL 33572
407-810-4176
pipiczinc@gmail.com
Pipicz Inc.

---------- Forwarded message ----------
From: **Bob Overmars** <bob@bpimedical.com>
Date: Wed, Jun 6, 2018 at 3:00 PM
Subject: Fwd: Intuitive Surgical da Vinci Endoscopic Instruments
To: "pipiczinc@gmail.com" <pipiczinc@gmail.com>

Literally 7 min prior to your email. Can you guys work the response?

If you do the work, I'll be the face 🤑

Sent from my iPhone

Begin forwarded message:

> **From:** "Rabang, Cal" <Cal.Rabang@fda.hhs.gov>
> **Date:** June 6, 2018 at 11:41:45 AM PDT
> **To:** Bob Overmars <bob@bpimedical.com>

Cc: "Chen, Long H" <Long.Chen@fda.hhs.gov>
Subject: RE: Intuitive Surgical da Vinci Endoscopic Instruments

Dear Bob Overmars,

Thank you for your patience; I hope to provide as complete and thorough of a response to your questions as I can offer.

§ Specifically for the reusable Endowrist Instruments, if the use-life counter is reset or extended past the number of available use lives, then the device specifications are changed. As such, you would be considered a remanufacturer per 21 CFR 820.3(w). In addition, if during the repair process the device is cleaned, disinfected and/or sterilized, then you would be considered a 3rd party reprocessor.

§ Remanufacturers and 3rd Party Processors meet the definition of "manufacturer" specified in 21 CFR 820.3(o) and are required to register and list according to 21 CFR 807.20. In addition, Endowrist Instruments are classified as **Class II** devices per 21 CFR 876.1500, Product Code NAY. As such, you would be subject to premarket notification (510(k)) requirements defined in 21 CFR 807.81.

I hope this provides enough explanation regarding the 510(k) requirements for repair of da Vinci reusable Endoscopic Instruments.

Please let me know if you have any questions/concerns.
Thanks,

Cal F. Rabang, Ph.D.
Biomedical Engineer
CDRH/ODE/DSD/GSDB2
U.S. Food and Drug Administration
Tel: 301-796-6412
Cal.Rabang@fda.hhs.gov
<image001.png>

Excellent customer service is important to us. Please take a moment to provide feedback regarding the customer service you have received: Click here for survey link

This communication is consistent with 21 CFR 10.85(k) and constitutes an informal communication that represents my best judgment at this time but does not constitute

an advisory opinion, does not necessarily represent the formal position of FDA, and does not bind or otherwise obligate or commit the agency to the view expressed.

From: Bob Overmars [mailto:bob@bpimedical.com]
Sent: Friday, June 01, 2018 1:03 PM
To: Rabang, Cal <Cal.Rabang@fda.hhs.gov>
Subject: Re: Intuitive Surgical da Vinci Endoscopic Instruments

Mr. Rabang,
Looking forward to hearing your response.

Can you let me know if you'll be responding and if so, would you have an estimate of when you will be responding?

Look forward to hearing from you.

Kindest regards,
Bob Overmars
President - CEO

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> On May 21, 2018, at 2:21 PM, Bob Overmars <bob@bpimedical.com> wrote:
>
> Mr. Rabang,
> Thank you for returning my call last week and explaining more about the 510K requirements for repairing da Vinci reusable Endoscopic Instruments.
>
> Intuitive sells these instruments non-sterile and they are provided cleaning and sterilization requirements in the packaging. After each use the hospital sterilizes them (like any other laparoscopic instrument) and puts them back up for the next case.
>
> Since its a reusable device, why is the FDA concerned about the repair facility having a 510K?
>
> We repair 1000's of reusable Endoscopic Instruments and the FDA does not require a 510K to repair those.
>
> Can you please help me understand?

Kindest regards,
Bob Overmars
President - CEO

<PastedGraphic-1.tiff>
Click the link below to our website for a video tour of our 38,000 ft. repair facility located in Seattle WA.
www.bpimedical.com
253-224-6090 C | 253-883-5040 O | 253-883-5041 F